



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-HBZC-03.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.



Authorized Signature (S)

Manufacturer

Name: Hubei Zhencheng Nonwoven Products Co., Ltd.
Address: Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China

Product Information

Name: Shoe Cover
Model: Non woven shoe cover, PE/CPE shoe cover
GMDN: 15056
Basic UDI-DI: /
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:



Date: 2021年3月1日

Position: General Manager Place: Hubei / China



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Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14683:2019+AC:2019 Type IIR

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-HBZC-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.



Authorized Signature (S)

Manufacturer

Name: Hubei Zhencheng Nonwoven Products Co., Ltd.
Address: Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China

Product Information

Name: Disposable Medical Face Mask
Model: earloop type, ties type
GMDN: 35177
Basic UDI-DI: /
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:



Date:

2021年3月11日

Position: General Manager

Place: Hubei / China



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Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-HBZC-02.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.



Authorized Signature (S)

Manufacturer

Name: Hubei Zhencheng Nonwoven Products Co., Ltd.
Address: Yanggang Industrial Park, Shazui Office, Xiantao, Hubei, China

Product Information

Name: Non woven cap
Model: mob cap, bouffant cap, doctor cap, round cap
GMDN: 32297
Basic UDI-DI: /
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:



Date: 2021年3月1日

Position: General Manager

Place: Hubei / China